$4,297–$4,587) higher; while the median quantile difference was $3,756 (95%CI: $3,636–$3,876). The quantile regression differences ranged from a low of $2,078 (95%CI: $2,012–$2,145) for the 5th quantile to a high of $8,691 (95%CI: $8,395–$8,987) for the 95th quantile. **CONCLUSIONS:** Results from econometric regression models can vary greatly depending on model assumptions. Quantile regression results provide a detailed picture of cost differences across the entire cost distribution, illustrating important non-uniformities of differences between groups.

**PRS49**

### TESTING THE USABILITY AND LANGUAGE OF E-PRO TRANSLATIONS DURING LINGUISTIC VALIDATION: COGNITIVE DEBRIEFING ON E-DEVICE VS. PRINT OUTSCREENSHOTS

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**OBJECTIVES:** Electronic data collection is a prominent evolution in the Patient-Reported Outcomes (PRO) field. Developing translations for e-formats must involve a rigorous methodology ensuring conceptual equivalence and cultural relevance across languages. Ideally comprehension and acceptability of translations should be tested using the actual e-device. For logistical reasons this may be challenging. Alternative methods include testing of translations using print outs of screenshots. The translation of an Asthma Diary into 20 languages was the opportunity to compare both methods. **METHODS:** (1) Identification of the languages using e-device testing versus those using screenshots; (2) comparison of the interview guides used for the respective testing methods; and (3) analysis and comparison of the results. **RESULTS:** A total of 15 languages were tested on the e-device, 5 with screenshots. The interview guide used to test the e-device contained linguistic considerations and questions on instructions and use of the device. The interview guide for the screenshots was purely linguistic in nature, so as not to confuse respondents with questions about the hypothetical use of the e-device. In terms of linguistic observations no differences were seen between the e-device and the screenshot testing methods. Feedback on the device usability differed by country but also across regions. In most countries/languages observations were made around the size of the font/screens and the device instructions. **CONCLUSION:** Testing translations using the actual e-device not only provides comprehensive feedback on the language of the items, but also information on the practical use of the device, and the interaction of both in the context of each country. Screenshot testing can be considered an alternative in cases where e-device testing is difficult.

**PRS50**

### EMPLOYING MULTI-ATTRIBUTE UTILITY THEORY TO DEVELOP THE EXACT-U: A PREFERENCE-BASED MEASURE FOR COPD EXACERBATION UTILITIES

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**BACKGROUND:** The EXACT (Exacerbations of COPD Tool) is a daily diary used in clinical trials to evaluate frequency, severity, and duration of COPD exacerbations. Reporting utilities from the EXACT allows a more accurate account of preference change for economic evaluations than current methods. Multi-attribute utility theory (MAUT) employs a series of equations to develop a function (MAUF) to report utilities. **OBJECTIVES:** To develop and validate an MAUF to estimate utilities from the EXACT for use in UK cost-effectiveness studies. **METHODS:** EXACT-U is comprised of 5 items with 3–5 levels each. Items and levels were grouped to form mixed-level and corner health states. Development group was used for MAUF construction; separate Validation group was used to test functions. UK general public respondents valued 11 health states (including best/worst) using TTO from full health/dead over 10 years. MAUF used the multiplicative model by: (1)-Calculating mean utility of each attribute level; (2)- Calculating group disutilities for each level; (3)-Applying multiplicative model to derive disutility function; and (4)-Converting disutility function to utility function. Performance assessed by: number of inconsistencies predicted, mean absolute error (MAE), and root mean squared error (RMSE). Models validated using a secondary analysis of a separate data set of EXACT patient data to test discriminant validity (statistical significance) and responsiveness (standardized response mean (SRM)). **RESULTS:** TTO interviews conducted with 400 respondents: 350 Development group, 50 Validation group. Respondents were: 36 yrs old (13.5 SD), 39.2% male, and 46.4% White British. MAUF reported MAE = 0.032, and RMSE = 0.170. Discriminant validity supported by utility differences by clinical severity: stable/acute ($P$ = 0.001); mild/moderate (p = 0.01); moderate/severe (p = 0.0001); and severe/very severe ($P$ = 0.14). Responsiveness by SRM was 0.52 (Day 3), 0.55 (Day 7), 0.66 (Day 10), and 0.76 (Day 13). **CONCLUSIONS:** The EXACT-U is a condition-specific preference-based measure to report COPD exacerbation utilities with minimal error, good discrimination, and good responsiveness.

**PRS51**

### ADVANCED PATTERN RECOGNITION METHODS FOR PREDICTING TREATMENT RESPONSE IN PATIENTS SUFFERING FROM ALLERGIC RHINITIS

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**OBJECTIVES:** The aim of the present analysis was to optimize the prediction of treatment response in patients with allergic rhinitis. To determine an optimal prediction accuracy, we used different Pattern Recognition (PR) approaches and evaluated their added value compared to standard predictive models as Logistic Regression, and Linear Discriminant Analysis. **METHODS:** In order to optimize the prediction of treatment response, 76,981 case reports of patient with allergic rhinitis from ten post-marketing-studies in Germany were analyzed by means of PR methodology. The processing steps applied within this study are: (a) feature extraction (genetic algorithm based synthetic feature calculation), (b) dimensionality reduction (correlation filter based feature selection, wrapper based feature selection, Principle Component Analysis based feature transformation), (c) classification (Support Vector Machine, Decision Tree, K-Nearest Neighbor, Random Forest, Artificial Neural Network, Bagging, Boosting Logistic Regression, Linear Discriminant Analysis), and (d) validation (leave-one-sample-out cross validation). **RESULTS:** The AdaBoost Support Vector Machine classifier with correlation filter based feature selection achieved the highest unweighted mean recall rate (mean of sensitivity and specificity; URR) of 62.8%. The standard Logistic Regression approach yielded 50.4% (–12.4%), the Linear Discriminant Analysis 50.6% (–12.6%). **CONCLUSIONS:** In comparison to standard learning schemes as e.g. Logistic Regression, and Linear Discriminant Analysis applying advanced PR methods improves substantially the prediction of treatment response in patients with allergic rhinitis. Due to the achieved added value and the superiority of Pattern Recognition methods within several benchmarking studies, advanced PR methods should be primarily considered for modeling and prediction tasks within the field of pharmacoeconomics.

## POSTER SESSION II

### CONCEPTUAL PAPERS & RESEARCH ON METHODS – Clinical Outcomes Methods

**PMC1**

### BEST PRACTICES IN REPORTING OF PROSPECTIVE OBSERVATIONAL STUDIES

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**OBJECTIVES:** Although a number of guidelines are available for the reporting of clinical trials and interventional studies, there is limited consensus in the structure, content and terminology associated with reporting of prospective non-interventional observational studies. The objective of this study was to describe best practices in reporting of observational studies based on a review of relevant guidelines for reporting data from clinical studies. **METHODS:** A systematic literature review was conducted and six relevant guidelines that could be adapted for reporting of results from prospective non-interventional observational studies were identified. The guidelines reviewed included the FDA guideline for abbreviated clinical study reports (CSR), the EMEA guideline for CSR, the International Conference on Harmonization (ICH) E3 guideline for CSR, Consolidated Standards of Reporting Trials (CONSORT) guideline for pragmatic trials, the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline and the International Society for Pharmacoepidemiology (ISPE) guideline for safety reports. The structure, content, and terminology used in the reporting template recommended by the various guidelines were analyzed. **RESULTS:** There were substantial differences in the structure, content and terminology recommended by the six guidelines. For example, in contrast to all other guidelines, the CONSORT guidelines mention "Objectives" under "Methods" instead of "'Introduction." Under the Results section, for reporting of unadjusted and adjusted estimates from outcomes data, the STROBE guideline recommends its inclusion within the *Main Results* section, whereas the CONSORT guideline recommends its inclusion within the *Outcomes and Estimation* section. Some guidelines, especially those focusing on interventional studies, were more similar in content. **CONCLUSIONS:** Based on the evaluation of similarities and differences in the guidelines, we propose a structure and template for reporting of prospective non-interventional observational studies. Recommendations are also provided for adapting the proposed template based on study objectives and design.

**PMC2**

### ESTIMATING COST-EFFECTIVENESS BASED ON RESULTS OF UNCONTROLLED CLINICAL TRIALS: OFATUMUMAB FOR THE TREATMENT OF FLUDARABINE- AND ALEMTUZUMAB-REFRACTORY CHRONIC LYMPHOCYTIC LEUKEMIA

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**OBJECTIVES:** Increasingly, innovative oncology drugs are licensed in settings where randomised controlled trials (RCTs) are ethically and/or practically infeasible. The